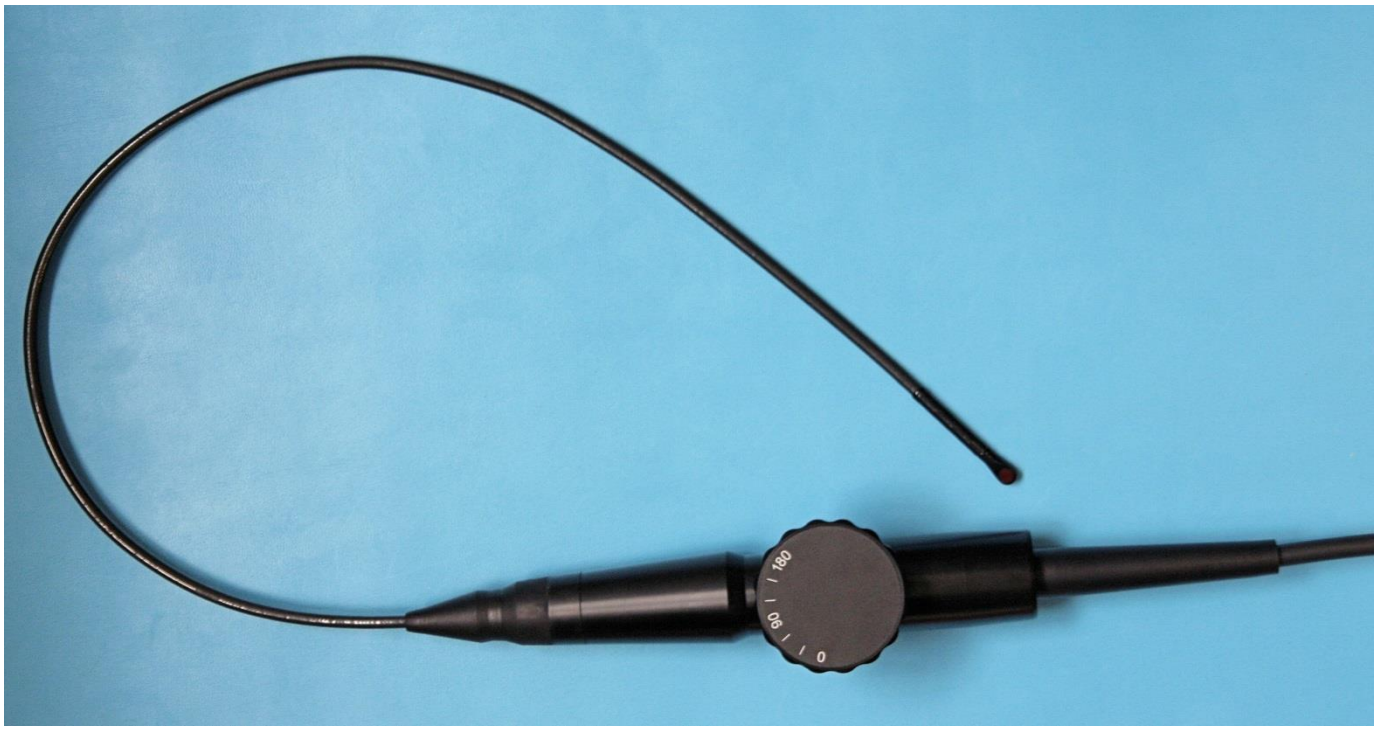
Oldelft Ultrasound

User Manual

Oldelft MicroMulti TE Probe

Type number 171Z-



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WARNING / CAUTION

- Before using the equipment, carefully study this manual.
  Keep this manual at hand for quick reference.
  Reread it periodically for warnings, safety precautions and maintenance requirements.
- **A damaged probe may cause an electrically hazardous condition when coupled to the human body.**
- **Do not use a damaged probe.**
- The MicroMulti TE probe is a precision instrument, which must be handled with care.
  It may be damaged when dropped or abused.
  In particular, do not allow the ultrasonic window in the tip to come into contact with a sharp object.
  Do not touch this window unnecessarily. Never exert force onto the window.
- **Only a qualified physician who has received appropriate training should perform examinations with the probe.**
- The connector is not watertight, and should always be kept dry.
  The control unit, although spray-watertight, should not be immersed.
- **This equipment contains no operator serviceable components.**
  To prevent electric shock, do not remove any covers or panels.
- **Inspect the probe for damage, cracks or bite-marks prior to each use.**
- Before introducing the probe: do not rub or spray the tip of the probe with an anaesthetic agent.
- **Please, do use the bite-guard, supplied with the probe.**
- Only use water-based coupling gel.
- As with all diagnostic ultrasound procedures keep exposure levels and duration to the minimum necessary for the examination, especially in the Doppler modes.
- **Avoid forceful manipulations and excessive force in using the probe, which could result in patient injury.**
  Withdraw the probe only with the deflection control in the unlock mode and with the distal end of the probe straight.
- Under normal conditions at full acoustic power the temperature of the tip does not exceed 43°C. Follow the instruction in this user manual to check this regularly.
- **Clean and disinfect as described in this user manual.**
- **Do not use methods not described in this user manual like Ethanol, Iodine, Steam, Heat or Ethylene Oxide.**
- **The up/down deflection may after prolonged use develop an unwanted amount of free play. In that case, contact the service organization to re-adjust the steering of the probe. In this way, the risk of "buckling" or "U-turning" of the probe in the esophagus is minimized.**

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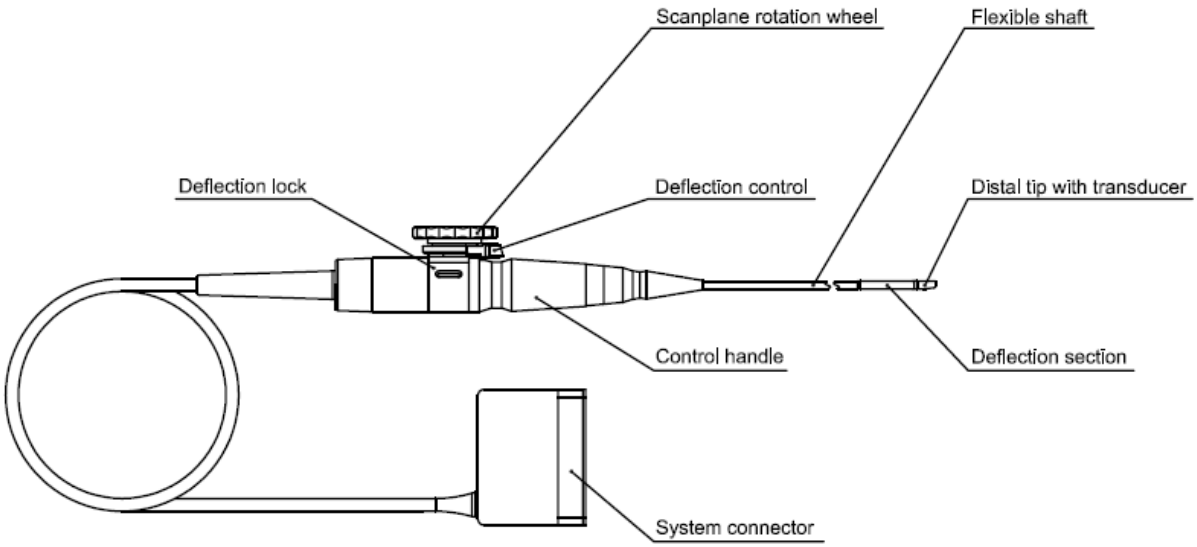
1. Introduction.

This document is written as such that it is conform the EN 1041:2008 standard.

1.1. MicroMulti TE Probes.

Oldelft manufactures the MicroMulti TE Probe with 32 elements, 6MHz phased array transducer, mounted in a sealed tip at the end of an gastroscope. The probe is intended for imaging of the heart through the esophagus and the stomach. The array can be rotated 180°. A manual rotation wheel on the handle of the probe controls the rotation of the scan plane. The deflection control wheel on the handle of the probe controls the deflection of the tip.



1.2. Intended use of the MicroMulti TE Probe.

WARNING **The MicroMulti TE Probe should be used only by a qualified physician who has received appropriate training in proper operation of the probe and in endoscopic techniques as dictated by current relevant medical practices.**

The physician conducting the examination must exercise sound medical judgement in the selection of patients for this probe and be skilled in interpreting the data obtained from the examination with the MicroMulti TE Probe.

MicroMulti TE Probe can be inserted via the nose of patients large enough to allow this, i.e. adult patients.

The probe can be used to form images of the heart to detect abnormalities, to evaluate the velocity of the blood flowing in the heart and to obtain a color depiction of the velocities of the blood flowing in the heart.

WARNING **The MicroMulti TE Probe is not intended for fetal imaging.**

1.3. Intention of this manual.

This manual gives the user all information necessary to guarantee a safe and satisfactory use of the MicroMulti TE Probe. It also describes how to handle the probe during all stages : before, during and after the examination.

2. Preparing the MicroMulti TE Probe for Use.

2.1. Visual examination.

Visually examine and feel all portions of the probe before use, especially the gastroscope shaft and the flexible section at the distal end of the gastroscope. Perform the inspection of the flexible section both with the probe deflection straight and deflected. There should be no discontinuities, bumps, dents, holes, abrasions, bite-marks or any other evidence of wear or damage found.

The hard plastic section at the distal end of the probe should be smooth and firmly attached to the gastroscope shaft.

The cable and the connector that attach the probe to the ultrasound console should be free from evidence of damage.

Check the proper mechanical operation of the probe. Rotate the scanplane with the scanplane rotation wheel on the handle (see §3.2). Make sure that the rotation is smooth for all scanplanes. Deflect the tip in both up and down direction using the deflection control wheel on the handle (see §3.2). Make sure the deflection operates smoothly.

Electrical Hazard **Any evidence of damage indicates the probe can not be used and should be returned to Oldelft for evaluation and repair.**

2.2. Safety precautions.

a. The MicroMulti TE probe is a precision instrument, which must be handled with care. It may be damaged when dropped or abused.
In particular, do not allow the ultrasonic window in the tip to come into contact with a sharp object.
Do not touch this **window** unnecessarily. Never exert force onto the window.

b. Only a qualified physician who has received appropriate training should perform examinations with the probe.

c. The connector is not watertight, and should always be kept **dry**.
The control unit, although spray-watertight, should not be immersed.

d. This equipment contains no operator serviceable components.
To prevent electric shock, do not remove any covers or panels.

e. Before introducing the probe: **do not rub or spray** the tip of the probe with an **anaesthetic agent**.

f. Avoid forceful manipulations and excessive force in using the probe, which could result in patient injury.

g. Withdraw the probe only with the deflection control in the unlock mode and with the distal end of the probe straight.

h. Never manually deflect the distal tip of the probe ; use only the deflection control wheel.

i. Do not kink, tightly coil, or apply excessive force on the probe cable or shaft. Insulation failure may result.

j. Under normal conditions at full acoustic power the temperature of the tip does not exceed 43°C. To check that the temperature increase of the tip is within limits :

- ❍ **Daily**
- ❍ **Weekly**
- ● **Monthly**
- ❍ **Other**

- ➢ Connect the probe to the Ultrasound system.
- ➢ Adjust the Acoustic Power to the highest value possible.
- ➢ Select Color Doppler mode.
- ➢ Wait for 2 minutes.
- ➢ Feel at the distal end of the probe if there is a relevant temperature increase, which could be harmful for the patient.

2.3. Preparation for Use.

Inspect the probe as described in §2.1.

Clean and disinfect the probe and the bite-guard as described in §4.

Make sure the system connector is plugged into the Ultrasound system and is locked by means of the locking handle on the connector.

For patient protection a sterile, single-use, latex sheath can be used.

CAUTION

Ensure that the sheath's sterile surface is maintained.

Devices containing latex may cause severe allergic reaction in latex sensitive individuals. Refer to FDA's March 29, 1991, "Medical Alert on Latex Products".

Place the bite guard on the probe so that after insertion of the probe the bite guard can easily be placed in the patient's mouth. The bite guard can also be placed in the patient's mouth before inserting the probe.

WARNING

The use of a bite-guard is mandatory. Failure to use the bite-guard may result in damage to the probe, which could result in a safety hazard. Damage to the probe due to biting is not covered by the probe's warranty.

Apply a sufficient amount of water-soluble acoustic coupling gel on the probe acoustic window.

CAUTION

Only use water-soluble acoustic coupling gel. Other coupling gels containing ingredients like ethanol, mineral oil, Iodine, lotions, lanolin, aloe vera or methyl or ethyl parabenzoic acid can cause probe damage.

If used, place the latex sheath over the probe and gastroscope shaft up to but not covering the handle. Rub the tip carefully to ensure that all air bubbles have been removed from the probe's acoustic window area. In addition to the gel on the acoustic window, apply a sufficient amount of acoustic coupling gel on the outside of the sheath at the tip of the probe.

CAUTION

Do not exert force on the window area.

3. Use of the MicroMulti TE Probe.

3.1. Patient selection.

Although the MicroMulti TE probe can provide clinical data not available from other instruments, there are some considerations to be made in patient selection for safe use of the probe.

CAUTION

The ability of a patient to swallow or accommodate the probe should be considered.

Any history of gastro-esophageal diseases must be determined and considered as well as the possible effects of other therapies the patient is undergoing.

All gastro-esophageal abnormalities must be considered as well.

3.2. Deflection and scanplane rotation control.

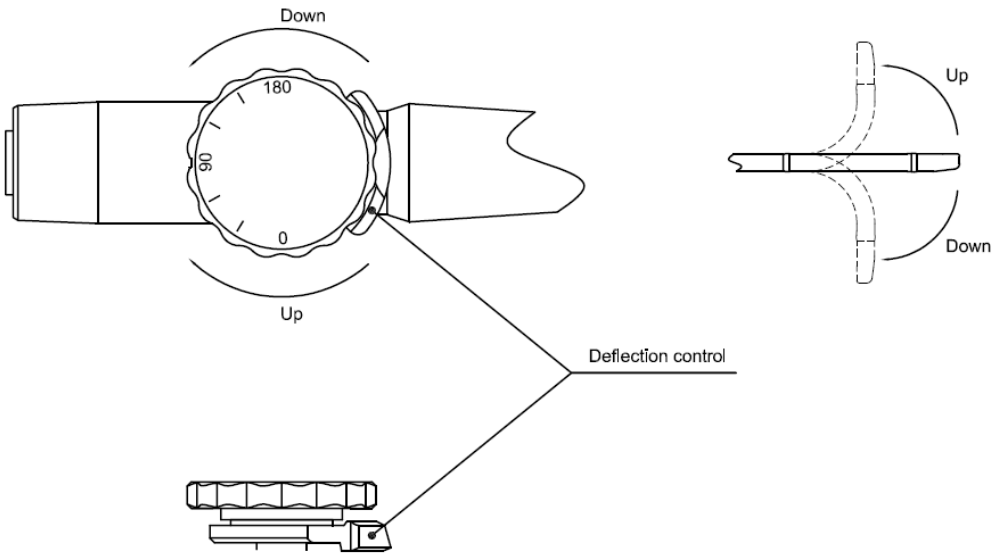
The control handle is designed for one-hand operation. Normally the operator takes the control handle in his left hand. Thumb, first and second fingers control the deflection and scanplane rotation control wheels.

The larger wheel on the handle is for controlling the probe tip deflection. This wheel has a locked and freely moving mode. In the locked mode the movement of the deflection wheel is restrained. This is used to hold the tip in a certain position. A metallic ring around the body of the handle, which clicks on/off, controls the lock.

The wheel on top is the scanplane rotation control wheel.

Tip deflection control.

The deflection control wheel found on the handle of the probe controls deflection of the MicroMulti TE Probe tip. A click is noticeable when the tip is in the natural (straight) position.

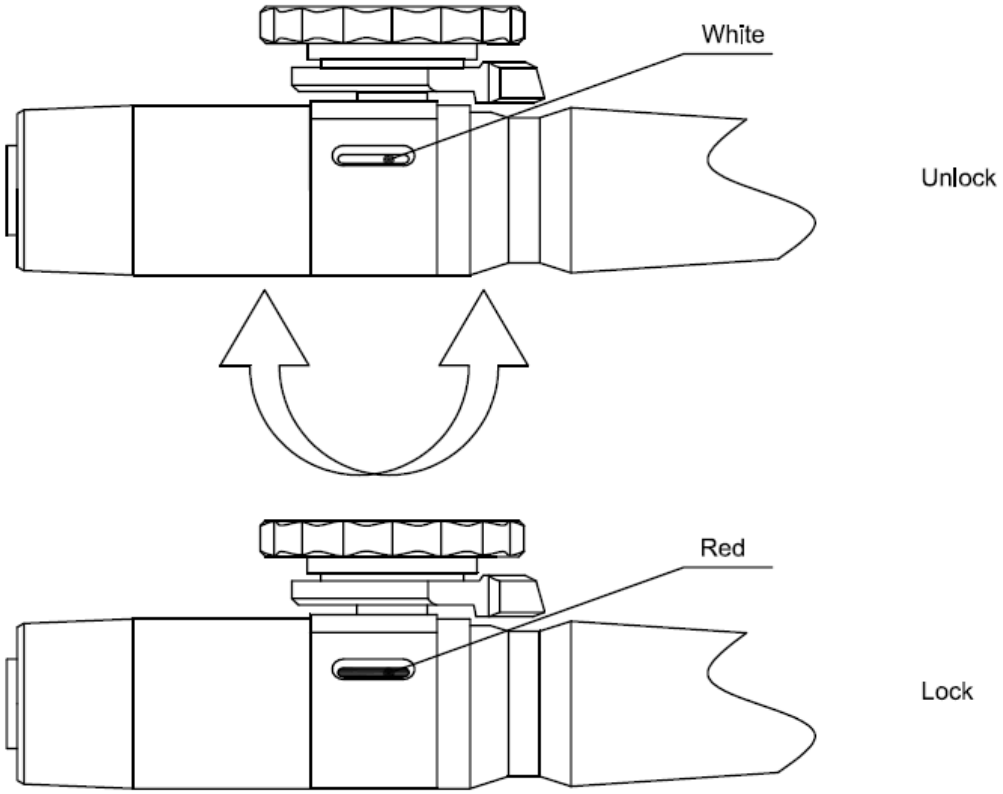


Tip deflection control.

WARNING **Check if the maximum deflection of the tip is 90° to 120° upward and 60° to 90° downwards. If the up/down deflection shows an unwanted amount of free play or exceeds the maximal deflection angles given above, do not use the probe. Contact the service organization to re-adjust the steering of the probe. In this way, the risk of "buckling" or "U-turning" of the probe in the esophagus is minimized.**

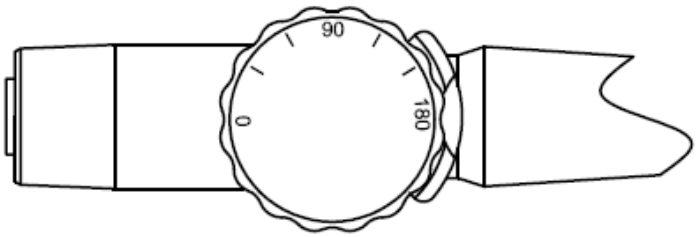
Lock operation.

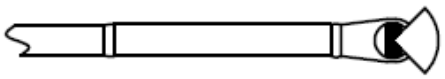
To protect the patient and the probe, unlock the deflection control when inserting or withdrawing the probe.

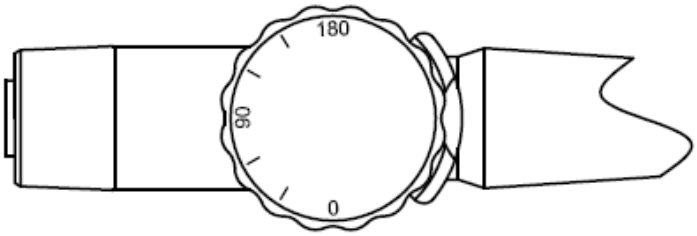


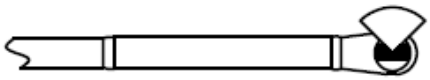
Transducer scanplane rotation control.

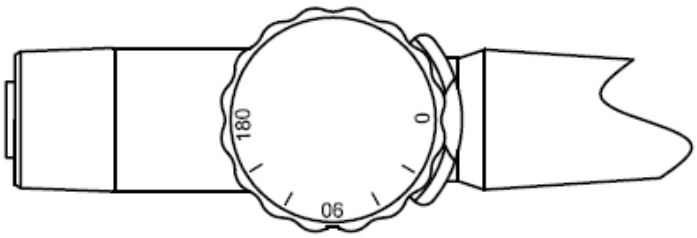
The transducer scanplane can be rotated from 0° (transversal plane) via 90° (longitudinal plane) to 180° (transversal plane, left/right inverted). All planes in between can also be chosen. This makes it possible to scan a conical imaging volume.

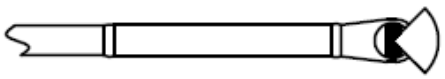












CAUTION

Do not use excessive force on the scanplane rotation control wheel at its outer positions as this may damage the gastroscope mechanism.

3.3. Examination.

The actual examination with the MicroMulti TE Probe is beyond the scope of this manual. There are many medical articles and books, which very thoroughly address this topic. There are however specific cautions that should be considered.

CAUTION

Long-term exposure to ultrasound should be minimized. Although there have been no confirmed adverse effects produced by diagnostic levels of ultrasound, unnecessary patient exposure to ultrasound energy should be avoided, especially in the Doppler mode.

Prolonged pressure on the esophagus by the tip of the probe may lead to a Pressure Necrosis phenomenon. Thus in monitoring applications the tip should be removed from the esophagus wall when you are not scanning by releasing it in the neutral position. If continuous monitoring is required the probe tip should often be re-positioned.

Whenever active scanning is not desired ‘freeze’ the image and release the deflection control.

Position the array such, that good acoustical contact is made. Before rotating the array, actuate the friction ('brake') on the up/down movement. If this is not done, rotating the array can mean loss of acoustical contact!

4. Cleaning and disinfecting the MicroMulti TE Probe.

Biological Hazard

Adequate cleaning and, if necessary disinfection are carried out to prevent disease transmission. It is the responsibility of the user to verify and maintain the effectiveness of the procedure used. A single-use, sterile disposable sheath for TE purposes can be used.

CAUTION

Keep the control handle and system connector out of any cleaning or disinfection solutions. The control handle and cable may be cleaned with a damp cloth, but only the distal end of the probe up to the 90cm marker on the shaft may be placed into a disinfection solution.

- ❍ **Daily**
- ❍ **Weekly**
- ❍ **Monthly**
- ● **Other**

After each use

Probe cleaning

a. Clean the tip and flexible shaft with gauze pads soaked in mild soapy lukewarm water (below 26°C is recommended). For other authorized cleaning agents, see Oldelft's website (www.oldelft.com).
b. Remove any materials that could interfere with the disinfection procedure.
c. Rinse the distal tip and shaft with lukewarm water, in which one can hold one's hand without pain. Proceed until all visible soap residue has been removed.

CAUTION

Do not clean any portion of the probe with methanol or ethanol. Such substance can cause irreparable damage to the probe.

c. Air-dry or dry with a soft cloth.

Probe disinfection

When necessary ultrasound probes can be disinfected using liquid chemical germicides. For other authorized disinfection liquids which have been tested for compatibility with the materials used to construct the probe, see Oldelft's website (www.oldelft.com). Follow the disinfectant manufacturer's recommendations for solution preparation, immersion time and rinsing.

d. Place the cleaned and dried probe surface in contact with the disinfection solution. Take care that only the distal end up to the 90cm marker is immersed.
e. Rinse the probe tip and shaft with water and dry prior to storage.

CAUTION

The probe should never be left in the disinfection solution for more than 1 hour.

Do not forget to rinse the probe directly after disinfection.

WARNING

Do not use other disinfection methods like Iodine, Steam, Heat or Ethylene Oxide.

5. Labeling

The device should be labeled by our customer in such way that the labeling includes the following items. Preferably the symbols used are conform the EN 980.

- CE mark of the vendor
- Reference to the Instruction for use
- Serial number
- Catalog number
- Date Of Manufacture
- Manufacturer
- BF applied part symbol
- Warning symbol

6. Storing the MicroMulti TE Probe.

The MicroMulti TE Probe is a sensitive and expensive instrument. Use great care when storing the probe. Make sure the probe is adequately cleaned and disinfected prior to storage.

The probe can be stored in its original case.

WARNING **Avoid damage to the probe by allowing nothing to protrude beyond the case when closing the lid.**

A wall mounted probe hanger can also be used for storage. Make sure the probe control handle, cable and connector are adequately supported. The shaft should hang down freely.

The storage environmental conditions must fall within the following range :

- Temperature between –10°C and 45°C.
- Humidity between 10% and 90%, non-condensing.

7. Specifications.

The probe is in conformity with the relevant provisions of the European Medical Device Directive 93/42/EEC. The probe is categorized in Class IIa.

The probe is classified according to IEC 60601-1 as class I, type BF, defibrillator-proof.

Mechanical dimensions	**171Z-**
➢ Shaft external diameter	5.2 mm
➢ Shaft length	90 cm
➢ Probe tip width	7.5 mm
➢ Probe tip height	5.6 mm
➢ Length of the inflexible distal part of the probe tip	18.5 mm

Transducer	
➢ Center frequency	6.0 MHz
➢ Type	phased array
➢ Number of elements	32
➢ Aperture	5.2 mm
➢ Focus	50 mm

Scanplane rotation minimum 180°

Tip deflection	
Up	120° ± 10°
Down	90° ± 10°

Leakage current / Dielectric strength
Meet the requirements of IEC 60601.

Biocompatibility
All external materials of the MicroMulti TE Probe have passed relevant biocompatibility tests according ISO 10993.

Environmental requirements

➢ Operating temperature	0 to 45°C.
➢ Storage temperature	-10 to 45°C.
➢ Relative Humidity	10 to 90%, non-condensing.

Annex A. Whom to Contact.

Manufacturer

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